

REMARKS/ARGUMENTS

Following entry of the present Response and Amendment, claims 1-66, and 80-121 remain in this application, with claims 1, 37 and 57 being written in independent format.

The Office Action first objected to the drawings for allegedly failing to meet the requirements of 37 CFR § 1.84(p)(4)-(5).

Additionally, the specification was objected to for allegedly containing various informalities.

The Office Action dated January 29, 2004 ("Office Action") rejected claim 87 under 35 U.S.C. § 112 as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

With respect to prior art, the Office Action rejected claims 1-9, 15, 28, 32, 36-39, 50-58, 62-65, 80-83 and 88-92 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,422,240 to Levitsky et al. (henceforth "Levitsky") in view of U.S. Patent No. 6,439,234 to Curti et al. (henceforth "Curti"). Further, the Office Action rejected claims 16-20 and 59 under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 5,626,131 to Chua et al. (henceforth "Chua"). Also, claims 20-26 and 60-61 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 6,467,477 to Frank et al. (henceforth "Frank"). Finally, the Office Action rejected claims 46-49 and 66 under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 4,602,644 to DiBenedetto et al. (henceforth "DiBenedetto").

Claims 10-14, 27, 29-31, 33-35, 40-45 and 84-86 were indicated as being directed to allowable subject matter, and were objected to in the Office Action only on the basis of being dependent claims referring to rejected independent claims.

In the present Response and Amendment, claims 6-9 and 15 have been cancelled without prejudice, claims 1, 10-12, 14-16, 27, 31-33, 37-41, 43-44, 48, 55-57, 62-63, 66, 84, 87 and 91 have been amended, and new claims 93-127 have been introduced for examination upon the merits. Claims 1-5, 10-14, 16-66, and 80-127 now remain in the application. These

amendments to the claims have been introduced to clarify the subject matter of the present invention, and to place the present application in better condition for allowance.

Additionally, the present Response and Amendment has certain apparent typographical errors identified in the specification.

Applicant submits that the above-requested amendments do not add prohibited new subject matter, and respectfully requests reconsideration of the merits of the present application in accordance with these amendments and the following remarks.

Specification Corrections

The requested amendments to the specification do not add any prohibited new matter, and merely correct readily apparent typographical errors present in the specification. In particular, Applicant has requested that the brief description of FIG. 5B and FIG. 6 found on page 10 of the original specification be amended as indicated such that they will be contained, as is common practice, in individual paragraphs.

Entry of these amendments to the specification are respectfully requested.

Claim Rejections

Each of the grounds for claim rejections is addressed below.

35 U.S.C. § 112

Claim 87 was rejected by the Office Action under 35 U.S.C. § 112 as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. In particular, claim 87 was submitted as a method claim dependent from an apparatus claim (claim 39). Claim 87 has been amended as appropriate to correct this typographical error.

Applicant notes that claim 87 was not rejected under any prior art in the Office Action, but was also not indicated as being directed to allowable subject matter. As claim 87 is directly dependent upon claim 39, which is ultimately independent claim 37, Applicant's remarks below specifically with respect to claims 37 and 39 provide support for the present allowability of claim 87 over the prior art of record.

Therefore, Applicant respectfully submits that this claim rejection has been obviated. Reconsideration and removal of this rejection is thus requested.

35 U.S.C. § 103(a) – applying Levitsky and Curti

Claims 1-9, 15, 28, 32, 36-39, 50-58, 62-65, 80-83 and 88-92 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over Levitsky as modified in light of Curti. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

Specifically in regard to independent claims 1, 37 and 57 as previously presented, the Office Action contends in pertinent part that Levitsky teaches an apparatus that delivers inspired gas to a person and samples expired gases from the person, where the apparatus includes an oral-nasal cannula having samplers for each nare and the mouth, and a diffuser grid for providing inspired gas. The Office Action further contends that Levitsky discloses an analyzer for the expired gas stream, and the use of a CO₂ sensor to measure CO₂ presence. The Office Action admits that Levitsky does not teach detecting when a person is inhaling or exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase, but alleges that Curti can be combined with Levitsky to overcome this deficiency. Applicant believes this obviousness rejection, insofar as it applies to the present claims, is inappropriate for various reasons and traverses as follows.

Levitsky pertains to cannula-type device for collecting expired gases from a patient with the purported benefit of reducing void volume within expired gas sampling lines (and thus eliminating problems in analysis caused by mixing, dilution collected samples). The Levitsky cannula includes a Y-shaped junction located between the nose and mouth where the tubes of the two nasal prongs and of an oral prong meet with a collection tube. The collection tube thereafter carries the gas to a downstream analyzer. An oxygen delivery tube, adapted to lie across the upper lip of the patient, is also disclosed. This delivery tube has two holes oriented below the nose of the patient intended to direct oxygen flow upward through a screen and to the nostrils of the patient for inhalation. Notably, as indicated in the Office Action, Levitsky does not address modulating the flow of delivered gas in any way.

Curti, which the Office Action purports to combine with Levitsky, discloses a split-

nare type nasal cannula which has a single fluid conduit prong for introduction up each nostril of the patient. One of the nasal prongs is connected to an oxygen source while the second nasal prong is connected to a gas analyzer. This separation of the nares in such a cannula is specifically addressed in the background portion of Applicant's specification at page 6, line 10, and within Levitsky at column 2, lines 28-47, and is described in both places as being undesirable in that it does not readily permit automatic control of sampling from various respiratory sites or account for the possibility that one nostril may be completely or partially obstructed compared to the other nostril, leading to poor oxygen delivery or sampling results.

Various embodiments of Applicant's invention, conversely, provide the ability to account for obstructed airways with prongs having fluid inlets that permit, as recited in claim 1, the collection of "expired gases individually from each of the two nares of the nose and from the mouth." This feature allows preferred embodiments of the invention, such as are recited, for example, in dependent claims 10-13, 27, 40, 43, 84-87, and 122 (reciting analyzing only expired gases from unobstructed nares or separate analysis of the nose and the mouth) and dependent claims 43-44, 100, 112 and 123 (reciting the use of two capnometers to analyze nose and mouth expired gases independently), to monitor and/or analyze each breath stream independently for monitoring ventilation, determining the breathing cycle, and/or for expired gas concentration sampling. The cannulas taught by both Levitsky and Curti do not provide this capability as an option, and in fact cannot provide this capability due to their inherent designs. Specifically, as depicted in FIG. 4, Levitsky combines the collected gas streams from its two nostril prongs with its single mouth prong at a Y-shaped junction immediately below the nose of the patient. In this manner, gases from the mouth and both nostrils are immediately mixed before the expired gases can be utilized to detect breathing or analyze respiration.

Similarly, Curti does not disclose a cannula having prongs with fluid inlets that permit the collection of expired gases individually from each of the two nares of the nose and from the mouth. The two nasal fluid conduits disclosed in Curti serve different purposes, with only one conduit positioned in a single nostril is utilized to collect expired gases (an no mouth fluid conduit being disclosed). Thus, individual collection of expired gases cannot be disclosed, taught, or suggested by Curti either, rendering any combination of Levitsky and

Curti defective to teach the present invention as recited in claim 1.

Further, claim 1 as presently amended recites that the fluid inlets for the particular nasal prongs are in communication with a sensor for detecting when said person is inhaling and exhaling. Levitsky does not disclose in any way the need to detect or how to detect when a patient is inhaling. Contrary to the assertions in the Office Action, Curti similarly does not disclose how to do such monitoring. While the referenced portion of Curti describes that its particular split-nare type cannula can be utilized with an intermittent oxygen delivery system that is adapted to provide oxygen only during inhalation, Curti does not describe any structure to perform that function. (Nor does U.S. Patent No. 5,626,131 cited within cited portion of Curti, and, coincidentally, also being invented by Chua et al. and having a substantially similar disclosure to the Chua reference relied upon in the Office Action.) In fact, the main focus of the Curti disclosure is centered on the use of holes within the walls of nasal prongs in a cannula to prevent occlusion and/or clogging of the nasal prongs during use. The specific structure as claimed by the Applicant cannot be rendered obvious merely by Curti baldly stating that its invention could somehow be modified to provide for intermittent oxygen delivery, or without some suggestion to one skilled in the art how to modify the simple sampling system as disclosed in Levitsky so as to produce the structure and perform the steps according to the present invention.

In this regard, Applicant respectfully submits that a *prima facie* case for obviousness has not been established in this case. In order to establish a *prima facie* rejection for obviousness, there must be found within the cited references some suggestion, teaching, or motivation to combine the references or modify a given reference to assemble the claimed combination. In the absence of such a teaching, the rejection is, at best, inappropriate hindsight analysis and is not proper. See In re Rouffet, 47 USPQ 2d 1453 (Fed. Cir. 1998); MPEP § 2142.

For these reasons, Curti cannot be considered to teach one skilled in the art how to modify Levitsky to produce Applicant's claimed invention. As such, claim 1 and all claims being dependent therefrom are patentable over the combination of Levitsky and Curti for these reasons alone.

Claim 37 as presently amended pertains to an apparatus for providing inspired gas to a

person and samples expired gases from the person which includes an oral-nasal cannula having sampling prongs for each nostril and for the mouth. Like claim 1, claim 37 recites the requirement that the prongs each have fluid inlets adapted to collect expired gases individually from the streams of expired gas emanating from each nare of the nose and from the mouth. Claim 37 further recites that the nare fluid inlets are in communication with a sensor that generates signals to said controller indicating when said person is inhaling and exhaling. As described above with respect to claim 1, neither Levitsky or Curti will be understood by one skilled in the art to collectively teach or suggest these features of the invention. Thus, claim 37 and all dependent claims are allowable over the prior art.

With regard to claim 57 as presently amended, Applicant has recited that inspired gas is supplied to the person using a cannula, and that the inspired gas is delivered through a plurality of holes located immediately about and partially surrounding the base of the nare prongs. As depicted and described in Applicant's specification at, for example, FIG. 10 and accompanying text, the arrangement of the plurality of fluid outlet holes immediately about the base of each nare tap provides for inspired gas flow that is diffuse so as to avoid discomfort, but which is also sufficiently directed and localized to the area proximate to the nares to minimize waste of inspired gas to the atmosphere. As described above, neither Levitsky nor Curti disclose, teach or suggest such a structure as claimed. Therefore, claim 57 and claims dependent therefrom are allowable over the cited art.

In light of the above remarks, Applicant respectfully requests reconsideration of all rejections based upon Levitsky and Curti. Applicant respectfully submits that these claims are allowable over the prior art, and appropriate reconsideration is requested.

35 U.S.C. § 103(a) – applying Levitsky, Curti and Chua

Claims 16-20 and 59 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of Chua. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action contends that Chua discloses an oxygen delivery system that utilizes a pressure sensor for detecting whether the person is inhaling, and concludes that the

teachings of Chua could therefore be combined with Levitsky and Curti to produce Applicant's claimed invention. Applicant respectfully submits that Chua does not remedy any of the above deficiencies described immediately above with respect to the combined teachings of Levitsky and Curti, and therefore cannot render the present claims obvious.

Specifically, while Chua may relate to the use of pressure analyzers to determine when a patient is inhaling/exhaling in order to control oxygen delivery, it provides no description of any structure or steps that would permit the simultaneous sampling of expired gases, monitoring of respiratory phase, and oxygen delivery as is claimed by the Applicant. Chua merely describes what it considers to be the optimal manner of timing the increase and decrease of oxygen delivery in an intermittent delivery system. Applicant has not found, nor has the Office Action cited, any teaching present in any of Levitsky, Curti or Chua would lead one skilled in the art to produce Applicant's invention as claimed. Therefore, in no way can the combination of these three references be considered to render Applicant's claims obvious.

Appropriate reconsideration is thus requested.

35 U.S.C. § 103(a) – applying Levitsky, Curti and Frank

Claims 20-26 and 60-61 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of Frank. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action alleges that Frank teaches the use of a humidity sensor and temperature sensor to detect whether the person is inhaling. Even if Frank discloses the use of humidity and temperature sensors to determine when a patient is inhaling/exhaling, that reference does not provide description of any structure or steps that would permit the simultaneous sampling of expired gases, monitoring of respiratory phase, and oxygen delivery, including the particular structure and steps discussed above with respect to the rejections base upon the combination of Levitsky and Curti. Therefore, the combination of these three references cannot be considered to render Applicant's claims obvious.

Appropriate reconsideration is thus requested.

35 U.S.C. § 103(a) – applying Levitsky, Curti and DiBenedetto

Claims 46-49 and 66 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of DiBenedetto. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action alleges that DiBenedetto teaches the use of a microphone to amplify a person's breathing to determine a respiratory phase. Even if DiBenedetto does teach how to use sound to determine a respiratory phase, this does not teach the invention as recited in claims 48, 49 and 66, so applicant respectfully traverses as follows.

Claims 48 and 49 depend from claim 37, and are thus allowable over the art for all the reasons discussed above with respect to the deficiencies of the combined teachings of Levitsky and Curti. Additionally, claim 48 (upon which 49 depends) recites the additional element of an auditory breath sonification device that includes a white noise generator that provides simulated breath sounds. Nowhere does DiBenedetto teach a white noise generator for providing simulated sounds. DiBenedetto uses a whistle-like sensor device for determining whether a patient is inhaling or exhaling according to the sound waves created by the breath stream's interaction with that sensor. It does not determine breathing, and then create simulated breathing sounds as is claimed.

Claim 66 recites the novel and nonobvious addition a sound lumen to the claimed cannula. The sound lumen connects the person to an auditory device that can create sounds for transmission to the person such that said sound lumen functions as a stimulus channel that carries an auditory prompt to the person. In no way does DiBenedetto discuss transmitting sound to the person for any reason.

Appropriate reconsideration of rejections based in part upon DiBenedetto is thus requested.

New Claims

In the present Response and Amendment, new claims 93-127 have been introduced for examination upon the merits. Applicant submits that support for these new claims can be found throughout the original specification, figures and claims, and that these new claims do

not introduce prohibited new subject matter into the application.

New claims 93-121 are directed to additional patentable features of the present invention. Notably, for example, new claims 93-96, 105-108, and 116-119 describe features of the invention relating to the positioning of fluid outlet holes around the nare prongs (such as is discussed above with respect to independent claim 57). Additionally, claims 103-104, 114-115, and 126-127 describe particular pressure sensing mechanisms for triggering the inspired gas delivery, which mechanisms are not present in the prior art. Further, claims 110, 112, 122, and 123 describe preferred embodiments of the invention that employ dual analyzers and/or capnometers advantageously to perform independent and/or comparative expired stream analyses.

Additionally, claims 102 and 125 pertain to a features of the invention that the Office Action indicated to be allowable subject matter.

Examination of these new claims upon the merits is respectfully requested.

Allowable Claims

Claims 10-14, 27, 29-31, 33-35, 40-45 and 84-86 were indicated by the Office Action as being directed to allowable subject matter, and were objected to in the Office Action only on the basis of being dependent claims referring to rejected independent claims. Applicant thanks the Examiner for the indication of allowable subject matter in this application.

Applicant notes, however, that of these allowable claims, claims 10-11 (and thus also claims 12-14 and 33-35 which are dependent therefrom), claim 31, claims 40-41 (and thus claim 42, dependent from claim 41), and claims 43-44 and 84 have been amended herein. These amendments preserve antecedent basis in light of amendments made to the independent claims, modify dependencies, and also clarify language found in the claims.

Entry of these amendments, and due consideration is requested.

Conclusion

In view of the foregoing, the Applicant respectfully requests that the Examiner consider the above-noted Response and Amendment when the claims are re-examined on its merits. A timely allowance of the pending claims is requested.

As the number of currently pending claims exceed the number of claims previously paid for by Applicant, "additional claims fees" are believed due at this time. A check is submitted herewith in an amount believed sufficient to cover this fee.

Additionally, Applicant has herewith submitted an Amendment Transmittal form requesting a three month extension of time for this Response and Amendment. The check submitted herewith also is intended to cover this fee.

If the amount of the check is insufficient to cover the required additional claims and extension of time fees, or is in excess of the required cumulative fee, please charge any necessary fees and/or credit any overpayments to Deposit Account No. 50-1349.

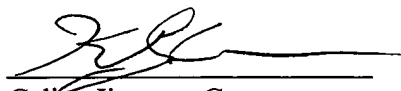
Additionally, if there are any other fees due in connection with the filing of this Response and Amendment that are not covered by the enclosed check, including any required extensions of time, please charge those other fees to Deposit Account No. 50-1349.

The Examiner is invited to contact Applicant's undersigned representative to expedite prosecution.

Respectfully submitted,

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